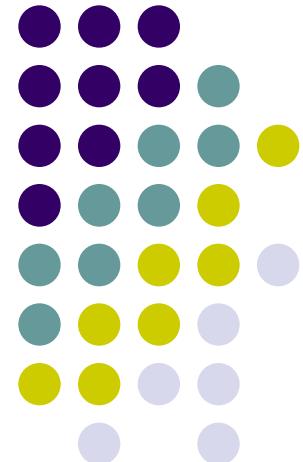
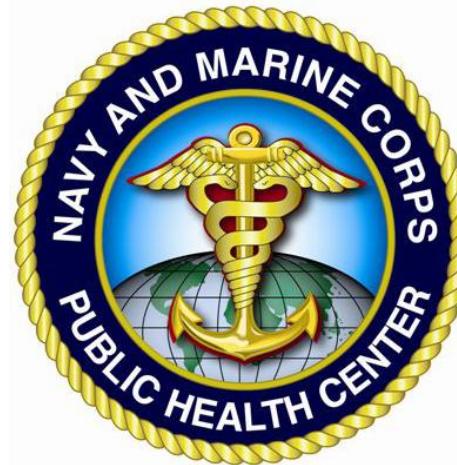


Lead Exposure at Navy Installations: Human Health Risk Assessment Methodologies



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7 May 2009

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Presentation Overview

- Why human health risk assessment (HHRA) for lead is unique
- Navy/DOD sources of lead
- Lead and lead-based paint regulations
- Lead HHRA under CERCLA
 - Toxicity assessment
 - Risk characterization using predictive blood lead models
 - Integrated Exposure Uptake Biokinetic (IEUBK) Model
 - Adult Lead Methodology
 - All Ages Lead Biokinetic Model
 - LeadSpread Model



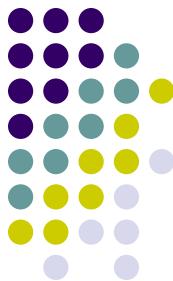
Why HHRA for Lead is Unique

- There is no cancer slope factor (CSF) for lead, thus no carcinogenic risk is evaluated.
- Non-carcinogenic health effects from lead exposure are evaluated using a **predictive model** tailored to a specific exposure scenario. These effects are predicted not with the reasonable maximum exposure but with the central tendency exposure.
- Risk management decisions for non-carcinogenic health effects are evaluated against the blood lead concentration of concern, not against a probability (10^{-6}).
- Lead HHRAs measure the contribution to total risk of adverse health effects from all exposure pathways.
- The contribution of blood lead from non-site related background sources is incorporated into the HHRA as the lead body burden (bioaccumulation in blood/tissues and bone).



Sources of Lead

- Munitions constituents (lead azide and lead styphnate are primary explosives, lead oxide is a propellant component); avgas; blasting caps, extinguishers, arming cartridges, etc.
- Major lead sources nationwide: lead-acid storage batteries, alloys such as brass in plumbing fixtures, nuclear and x-ray shielding, etc.
- Lead-based paint (LBP)
- Naturally occurring lead compounds (ubiquitous)
- Anthropogenic background sources include leaded compounds for vehicle exhaust, stack emissions from industrial processes, and pesticide application.



Regulations pertaining to Lead

- Environmental sources of lead
 - CERCLA – release of lead into environment
 - RCRA – actions involving lead waste
- LBP
 - CERCLA is not applicable to the removal or remedial action upon products which are part of the structure of, and result in exposure within, residential buildings or business or community centers.
 - Title X of the Lead-Based Paint Hazard Reduction Act, shared jurisdiction of HUD and EPA; applies to everyone
 - Lead-Based Paint Guidelines for Disposal of Residential Real Property – A Field Guide; DOD only (applicable to transfer of residential real property)



Lead-Based Paint

- Title X – subtitle of Housing and Community Development Act of 1992, works in conjunction with TSCA
 - HUD involvement – regulates activities concerning the presence of LBP, such as the inspection of surfaces and LBP risk assessment
 - EPA involvement – defines LBP hazard and dictates procedures for LBP hazard abatement (such as 40 C.F.R. Part 745, Lead; Renovation, Repair, and Painting Program)
- Field Guide – an agreement between DOD and EPA that DOD will follow Title X provisions, except
 - Mandates that potential soil lead hazards around dwellings should be evaluated for the need for abatement.
 - Use of interim controls should be considered based on the likelihood of lead exposure to children.

Lead HHRA under CERCLA



Construct conceptual site model (CSM) and evaluate for complete exposure pathways.
Determine average soil lead concentration at the site, and compare it with EPA Regional Screening Levels (RSL).

Tier IA

If average site soil lead concentration is less than RSL,
STOP. No further action is required unless special
circumstances warrant further study.

If average site soil lead concentration is greater than RSL,
update and refine the CSM and exposure scenario. Develop
site specific risk-based screening concentrations (RBSC) and
compare with site concentrations. If the site concentrations do
not exceed the RBSC, the HHRA may be exited.

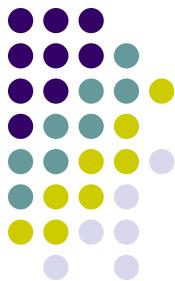
Tier IB

If RBSC is exceeded, collect site-specific data based on the
refined exposure scenarios. Sampled media would include soil
and dust at a minimum, and may include water, air, and diet.
**Run predictive blood lead model with site-specific data to
predict blood lead concentrations for the exposed populations.**
If the site does not pose an unacceptable risk to human health,
the HHRA may be exited.

Tier II

Run predictive blood lead model with site-specific data to
develop site-specific risk-based cleanup levels.

Tier III



Tiered HHRA Process

- Risk-Based Screening - Tier I

A residential soil RSL of 400 mg/kg was calculated by USEPA as the level where a 'typical' response (i.e., the normal incidence of exceeding a blood lead concentration of 10 µg/dL), is expected for exposures to national averages for background lead concentrations. For industrial soil, the RSL is 800 mg/kg.

- Baseline HHRA – Tier II

- Data evaluation and reduction
- Exposure assessment - **identification of potentially exposed populations is important**
- **Toxicity assessment**
- **Risk characterization**



Toxicity Assessment

- USEPA characterizes lead as a probable human carcinogen (Class B2) (EPA IRIS), but no CSF is available.
- Prominent noncarcinogenic health effects from exposure to lead are its neurotoxic properties and effects on the neurodevelopment of children. Adults may experience damage to several organ systems, such as neurological damage, adverse musculoskeletal effects, and adverse cardiovascular system effects such as hypertension.
- The blood lead concentration of concern established by the CDC as 10 µg/dL, because impairment of the developing central nervous system, learning dysfunction, and behavioral disorders were found in children aged 0 to 6 years at this concentration.

Risk Characterization through predictive blood lead models



- Lead BHHRAs require a biokinetic model to characterize noncarcinogenic health effects. These models predict a distribution of blood lead concentrations for an exposed population which can then be compared to 10 µg/dL to determine if remedial action or intervention is warranted.
- Each model employs a set of parameters that incorporate knowledge gleaned from the other three components of the HHRA, which is converted into useable information that can be considered with risk management options.



Risk Model Parameters

- Soil concentration is the most important parameter for the predictive BL models; thus it must be site-specific.
- Indoor dust: Potential for inhalation of dust lead is heightened due to its presence on surfaces which children and their toys could have frequent contact. If dust lead sampling is not possible, a default approach must be used. This approach assumes that 70% of the lead in indoor dust is contributed by soil, and the result is known as the mass fraction of soil in dust (M_{SD}).
- Exterior LBP: When soil and dust lead levels are measured and used to predict blood lead concentrations, the contribution of LBP to overall exposure is already accounted for.
- Drinking water: The parameter default value (4 $\mu\text{g}/\text{L}$) is sufficiently representative, based on drinking water targets.
- Airborne lead: The parameter default value (0.1 $\mu\text{g}/\text{m}^3$) is sufficient as this is a relatively insignificant contributor to blood lead.



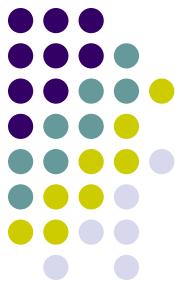
IEUBK Model

- The IEUBK model is for residential exposure scenarios.
- Based on the USEPA risk management goal to limit exposure so that there is a less-than-5% probability in an exposed population that an individual child's (aged 0 to 84 mos.) blood lead concentration will exceed 10 $\mu\text{g}/\text{dL}$. Applicable to residential exposure.
- Four functional components are used to create a plausible distribution of blood lead concentrations: exposure, uptake, biokinetic, and probability distribution.
- Distribution is centered on the geometric mean blood lead concentration (the central tendency exposure), and uses a default value geometric standard deviation. From this distribution the probability that an blood lead concentration for a hypothetical child will exceed the 95th percentile blood lead concentration is calculated.



Adult Lead Methodology

- ALM is Recommendations of the Technical Review Workgroup for Lead for an Interim Approach to Assessing Risks Associated with Adult Exposures to Lead in Soil
- Describes a method that can be used to predict blood lead concentrations due to soil lead exposure at non-residential sites.
- Approach of predicting blood lead concentrations is based on relating the amount of soil lead ingested by a woman of child-bearing age to the blood lead concentration in her hypothetical fetus.
- Based on assumption that a non-residential site will have a worker population with at least one woman who will become pregnant while employed at the site or within several years after cessation of exposure.
- Calculates the total blood lead concentration for a pregnant woman (and thus her fetus) by adding the incremental increase in blood lead concentration resulting from a steady pattern of site exposure to the body burden of lead.



All Ages Lead Biokinetic Model

- All Ages Lead Biokinetic Model is currently being constructed by EPA. Model conceptual structure and design are not available yet (late 2009/2010).
- Predict blood lead for any hypothetical individual of any age/population at-risk.
- Apparently structurally similar to the IEUBK Model, as it employs both an integrated multimedia exposure design and a complex biokinetic module.



LeadSpread Model

- LeadSpread created by the California Department of Toxic Substances Control and should be used for sites in California.
- Predict blood lead concentrations in an average or pica child (1 to 2 years old), and residential or occupational receptors.
- Predicted blood lead concentration is an integrated measure of internal dose from site-specific and background sources. The equation for each exposure pathway derives a linear slope which are then summed to find total blood lead.



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